

## **REMARKS**

### **A. BACKGROUND**

The present Amendment is in response to the Office Action mailed April 27, 2010. Claims 1, 2, 4-17, 19-21, and 24-40 were pending and rejected in view of cited art. Claims 1, 14, 30, and 40 are amended. Claims 1, 2, 4-17, 19-21, and 24-40 remain pending in view of the above amendments.

Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action.

Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, are consistent with the Examiner's understanding.

### **B. PRIOR ART REJECTIONS**

#### **I. REJECTION UNDER 35 U.S.C. § 103**

As presented herein for reconsideration (see independent claim 1, as exemplary), the invention claimed in independent claim 1 includes a device for sealing a puncture extending through tissue proximal to an interior vessel surface. The device includes a first disk having a self-expanding first bare wire frame that forms a plurality of petals, the plurality of petals having a first end and a second end, each petal of the plurality of petals is joined to the remaining petals of the plurality of petals at a joint. A proximal element having a second bare wire frame is coupled to the first bare wire frame. The first disk is configured to be rotatably coupled to the proximal element in a delivery configuration to allow altering of a distance between the first disk and the proximal element. The first disk has a retracted delivery configuration configured for delivery to the puncture and an expanded deployed configuration in which the first disk is configured to engage with and substantially conform to the interior vessel surface, and the proximal element is configured to engage the tissue proximal to the interior vessel surface.

The Office Action rejected claims 1, 2, 4-6, 8, 11, 13-16, 19-21, 24, 30-35, 38, and 40 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Pub. No. 2003/0055455 (Yang) in view of U.S. Pat. No. 7,431,729 (Chanduszko). Claims 7, 9, 36, and 39, were rejected under 35 U.S.C. § 103(a) as being unpatentable over Yang in view of Chanduszko, as applied to claims 1 and 30 and further in view of U.S. Pat. No. 6,080,182 (Shaw). Claims 10 and 37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Yang in view of Chanduszko, as applied to claims 1 and 30 and further in view of U.S. Pat. No. 5,855,614 (Stevens). Claims 12 and 17 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Yang in view of Chanduszko, as applied to claims 1 and 14, and further in view of U.S. Pat. No. 6,949,113 (Van Tassel).

Applicant respectfully submits that the independent claims as presented for reconsideration are not anticipated nor made obvious by Yang either singly or in combination with any other reference of record.<sup>1</sup> In particular, Yang discloses "[s]ystems and methods for treating septal defects" (Abstract). As described, the system includes a "first catheter and a second catheter [that] may be steered to opposite sides of a septal defect" to deliver the separate first and second patches (para. [0007]). Once a bridge member is extended through the septal defect and between the first catheter and the second catheter, the two patches (one from the first catheter and one from the second catheter) are urged together and "connectable across the septal defect" (Para. [0008]). The two patches are not connected together in the delivery configuration because they are "connectable across the septal defect" from two different catheters. As such, Yang provides no teaching or suggestion that the two patches are "connected in a delivery configuration." Further, Yang teaches away from toward being "connected in a delivery configuration," because any modification of Yang in view of other cited art of record would defeat the purpose of Yang by completely changing the principal of operation of delivering the two patches from different sides of the septal defect.

Chanduszko discloses "a device for occluding an anatomical aperture, such as a septal defect or patent foramen ovale" (Abstract). As described, "distal side 30 and proximal side 40 of occlude 20 are connected by intermediate joint 22. The intermediate joint 22 secures the wires of the device and, according to some embodiments, may be a weld, solder or tube" (col. 7, ll. 4-8). This connection appears to be fixed and not capable of being used to alter the distance of the

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<sup>1</sup> Any amendments to claims other than those which are expressly relied upon in overcoming the rejections on art have been made simply to insure consistency in claim language, to correct typographical or grammatical errors, or to correct other errors of a formal, non-substantive nature, but not to otherwise narrow the claims in scope for any reason.

two disks relative to each other. In another configuration, the intermediate joint 22 may be a spring, e.g. a coil spring” (col. 7, ll. 20-21); however, no mention is made of this “coil spring” translating along a portion of the proximal element to alter the distance between the two disks.

Thus, Yang and/or Chanduszko clearly do not anticipate or make obvious Applicant’s claimed device (e.g., see claims 1, 14, 30, and 40) which requires, *inter alia*,

- “a first disk having a self-expanding first bare wire frame that forms a plurality of petals, . . . *each petal of the plurality of petals is joined to the remaining petals of the plurality of petals at a joint*” and “a proximal element having a second bare wire frame coupled to the first bare wire frame, the first disk being coupled to the proximal element *in a delivery configuration and translating along a portion of the proximal element to allow altering of a distance between the first disk and the proximal element*” (Claims 1, and 30, emphasis added) or alternatively, “the first disk and the second disk being connected *in a delivery configuration and the first disk translating along a portion of the second disk to allow altering of a distance between the first disk and the proximal element*” (Claim 14, emphasis added), or alternatively, “the first disk and the proximal element being connected *in a delivery configuration and translating along a portion of the proximal element to allow altering of a distance between the first disk and the proximal element*” (Claim 40, emphasis added).
- “the first disk including a first threaded member and the proximal element including a second threaded member, the first and second threaded members being configured for releasably coupling the first disk to the proximal element *in the delivery configuration and translating the first disk along a portion of the proximal element to allow altering of a distance between the first disk and the proximal element.*” (Claims 30, emphasis added)
- “a first disk having a self-expanding frame, *without coatings or membranes, . . . each petal of the plurality of petals is joined to the remaining petals of the plurality of petals at a joint*” (Claims 40, emphasis added), (Emphasis added).

Accordingly, for at least the reasons noted, independent claims 1, 14, 30, and 40 and the claims depending therefrom<sup>2</sup> are neither anticipated nor made obvious by Yang and/or

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<sup>2</sup> Emphasis herein of the differences between the independent claims and the prior art are equally applicable to the dependent claims, but this does not mean, on the other hand, that these are necessarily the *only* differences between the claimed invention and the prior art of record. Applicants thus do not acquiesce in any asserted rejections of the dependent claims.

Chanduszko, either singly or in combination with any other cited prior art of record<sup>3</sup>, and thus reconsideration and withdrawal of the rejection under Section 103 is respectfully requested.

**C. CONCLUSION**

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in the last action regarding the cited art or the pending application, including any official notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in the last action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as provide the required motivation or suggestion to combine references with the other art of record.

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<sup>3</sup> Shaw, Stevens, and Van Tassel were cited as secondary references. Shaw was cited for the proposition that it discloses "the proximal element being a spring" and "at least one delivery element constrained to translate a maximum distal depth" (Office Action, p. 3). Stevens was cited for the proposition that it discloses "the first disk and the proximal element comprise barbs, hooks, sharp edges, or roughened surfaces," and Van Tassel was cited as disclosing "a coagulant-enhancing agent that is disposed on a disk." (Office Action, p. 4). That said, none of these references otherwise add anything in terms of reading on the claims as amended herein, particularly in reference to those claimed limitations noted above which clearly define over Yang and/or Chanduszko. Thus, even assuming *arguendo* that any of the references to Shaw, Stevens, and Van Tassel are properly combinable with Yang and/or Chanduszko, such combinations are clearly distinguished by the claims for the reasons already noted in reference to Yang and/or Chanduszko.

Furthermore, Applicant respectfully disagrees with the characterization of Stevens as disclosing "barbs, hooks, sharp edges, or roughened surfaces" because the identified portion of Stevens only references the inclusion of "points" with no additional discussion regarding same.

For at least the foregoing reasons, Applicant respectfully submits that the pending claims are neither anticipated by nor made obvious by the art of record. In the event that the Examiner finds any remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney.

Dated this 27<sup>th</sup> day of July, 2010.

Respectfully submitted,

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